THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte TIMOTHY A. McCAFFREY
and DOMENICK J. FALCONE

_____

Appeal No. 94-4393
Application 07/692,921[1]

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REMAND TO THE EXAMINER

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Before RONALD H. SMITH, WILLIAM F. SMITH, and GRON, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

[1] Application for patent filed April 29, 1991.

REMAND TO THE EXAMINER

We remand this application for the examiner to consider the following issues and take appropriate action.

Representative Claims

Claims 1, 4, 7, and 9 are illustrative of the subject matter under review in this appeal and read as follows:

1. A method for depleting heparin of a heparin subspecies with high or low affinity for transforming growth factor-beta which comprises:

providing a polypeptide containing a heparin-binding region of TGF-$;

immobilizing the polypeptide on an insoluble substrate;

contacting the immobilized polypeptide with heparin for a sufficient time to allow binding; and

collecting the unbound heparin.

4. A method according to Claim 1 which further comprises purifying the unbound heparin.

7. A purified Heparin subspecies having anticoagulant activity and which does not bind to transforming growth factor $.

9. A method for purifying heparin fractions with high or low affinity for transforming growth factor-beta which comprises:

providing a polypeptide containing a heparin-binding region of TGF-$;

immobilizing the polypeptide on an insoluble substrate;

contacting the immobilized polypeptide with heparin for a sufficient time to allow binding;

collecting the unbound fraction;

collecting the bound fraction; and

concentrating the bound and unbound fractions.

Inconsistent Rejections

Claims 1 and 7 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The examiner considers the word "subspecies" to be vague and indefinite. Claims 1 and 9 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The examiner considers these claims to be indefinite for failure to "set forth specific steps in the process of using the instant invention" (Examiner's Answer, page 3).

In regard to the rejection of claims 1 and 7, we note that claims such as claim 4 which depend from claim 1 do not further define or in any other way provide any further meaning to the word "subspecies" as this word is used in claim 1. Thus, it is not clear why claim 4 as well as the other claims dependent from claim 1 are not included in the rejection of claim 1 for this reason. The second rejection suffers from the same defect. Again, the claims which depend from independent claims 1 and 9 do not correct the alleged defect in

the rejected claims. Thus, it is not clear why the claims which depend from claims 1 and 9 are not included in the second rejection.

On return of the application, the examiner should review the two rejections and all of the pending claims and ensure that the claims are consistently treated.

Relevant Legal Standards

In reviewing the statement of the two rejections which appears on pages 3-4 of the Examiner's Answer, it does not appear that the examiner used the appropriate legal standard in considering issues raised under 35 U.S.C. § 112, second paragraph. For example, in rejecting claims 1 and 7, the examiner merely questioned whether the word "subspecies" is vague and indefinite. In so doing, it does not appear that the examiner has reviewed the supporting disclosure of this application or relevant prior art in an attempt to determine whether appellants' use of this word is appropriate. The relevant legal standard for determining definiteness of claim language is set forth in In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). Therein, the court stated that "definiteness of the [claim] language . . . must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." Moore at 1234, 169 USPQ at 238 (footnote omitted).

Here, it appears that the examiner considered the definiteness of the word "subspecies" in a vacuum. This is incorrect. Rather, the examiner must analyze the supporting disclosure of this application and relevant prior art, e.g., the twelve references cited in the Amendment After Final rejection (Paper No. 18, September 3, 1993).

The examiner should also note that claims 9 through 13 do not use the word "subspecies" but rather, are directed to so-called heparin fractions. The examiner has not found the word "fraction" to be indefinite. It appears from reading the specification of this application that appellants use the two words interchangeably. If so, since the examiner has no apparent problem with appellants using the word "fraction," this issue might be simply resolved by the examiner allowing appellants to amend the relevant claims to use the word "fraction" or "fractions" instead of the objected to word "subspecies."

Adequacy of Prior Art Search

1. Classes and Subclasses.

The "SEARCHED" portion of the file jacket of this application indicates that a single class and subclass, Class 530, Subclass 328, has been searched by the examiner. That subclass appears to be most relevant to the 10 amino acid polypeptide set forth in claim 6 on appeal. It does not appear that the examiner's search of the classes and subclasses took into account all of the claims on appeal. It would appear that classes and subclasses

such as Class 530, Subclass 412+, and Class 536, Subclass 21, would be relevant areas to search for the subject matter of the broader claims on appeal.

Upon return of the application, the examiner should review all the claims pending in this application and ensure that all relevant classes and subclasses have been searched.

2. Computer Databases.

The "SEARCH NOTES" area of the file jacket of this application indicates that certain computerized databases have been searched. Among the databases searched was the database which contains amino acid sequences. The "ONLINE SEARCH REQUEST FORM" (PTO-1542), which is of record in this application, indicates that the amino acid sequence data base was searched on the basis of the 10 amino acid residue polypeptide of claim 6. But in listing that sequence when the search was commissioned, the examiner appears to have misidentified the Leu residue at position 6 of the polypeptide of claim 6 as Ile. From this record, it appears that the search was performed on the basis of an incorrect sequence.

Upon return of the application, the examiner should determine whether the polypeptide of claim 6 has been properly searched on the available computerized databases. If not, the examiner should see to it that a correct search is performed.

Claim 7

It does not appear that the examiner has separately considered the patentability of product claim 7. Claim 7 is directed to a purified heparin subspecies or fraction which has anticoagulant activity but does not bind to TGF-$. The 12 references cited by appellants referenced above indicate that numerous workers have separated heparin into various fractions for a variety of reasons. It does not appear from this record that the examiner has considered that such prior art may be relevant in determining the patentability of claim 7. Consider In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) wherein the court held that under appropriate circumstances the Patent and Trademark Office (PTO) can require an applicant to establish that prior art products do not necessarily or inherently possess the characteristics of the claimed product.

Upon return of the application, the examiner should review all relevant prior art concerning separating heparin into various fractions as well as relevant legal precedent such as Best. The examiner should determine whether the prior art describes heparin fractions under circumstances where it would be reasonable to shift the burden to appellants to establish whether such fractions necessarily or inherently possess the characteristics required by product claim 7.

This application, by virtue of its “special” status, requires an immediate action. MPEP § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMAND

Ronald H. Smith Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Teddy S. Gron Administrative Patent Judge	)

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